REMARKS

Claims 1-19 are pending in the application.

Claim 14 is withdrawn from consideration, but Applicant is requesting reconsideration of this claim, as set forth below.

Claims 1-13 and 15-19 have been rejected.

Claims 1, 3, 4, 6-9, 11, 14 and 16 have been amended, as set forth herein.

Claims 2, 5 and 13 have been canceled, without prejudice.

I. EXAMINER INTERVIEW

Applicant thanks the Examiner for holding the in-person interview with the Applicant's representatives, Mr. Peter Lando and Mr. Terry Daglow, on October 13, 2004.

II. REJECTION UNDER 35 U.S.C. § 112

Claims 1-3, 6-13 and 15-18 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, though enabling for "wherein the greatest transverse dimension of the body of the lead is less than a corresponding interior dimension of the percutaneous introduction structure", does not reasonably provide enablement for "wherein the greatest transverse dimension of the lead is less than a corresponding interior dimension of the percutaneous introduction structure: as set forth in independent Claims 1, 6, 8, 11 and 16. The rejection is respectfully traversed.

Applicant has amended the claims to recite that the greatest transverse dimension of the body of the body of the lead is less than a corresponding interior dimension of the percutaneous introduction structure. Support may be found in the specification, paragraph 0015.

Accordingly, the Applicant respectfully requests withdrawal of the § 112 rejection of Claims 1-3, 6-13 and 15-18.

III. REJECTION UNDER 35 U.S.C. § 102

Claims 1-13 and 15-19 were rejected under 35 U.S.C. § 102(e) as being anticipated by King, et al. (US 6,161,047). Claims 1-7 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kuzma, et al. (US 6,522,932). Claims 1-13 and 15-19 were rejected under 35 U.S.C. § 102(e) as being anticipated Errico, et al. (US 6,175,769).[1] The rejections are respectfully traversed.

A cited prior art reference anticipates the claimed invention under 35 U.S.C. § 102 only if every element of a claimed invention is identically shown in that single reference, arranged as they are in the claims. MPEP § 2131; *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). Anticipation is only shown where each and every limitation of the claimed invention is found in a single cited prior art reference. MPEP § 2131; *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985).

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[1] This rejection alternatively rejected Claims 1-13 and 15-19 as being obvious over Errico, et al. (US 6,175,769) in view of Kohnen, et al. (US 6,249,707).

Applicant has amended the claims such that each of the independent Claims 1, 4, 6, 8, 11 (and the withdrawn independent Claim 14) now recite: (1) that a greatest transverse dimension of the body of the lead when outside the percutaneous introduction structure is less than a corresponding interior dimension of the percutaneous introduction structure (emphasis added); and (2) a channel extending from a proximal end of the lead to a position within the body of the lead, wherein the channel is adapted to receive a stylet. Support for element/feature (1) may be found in the Specification, paragraph 0015, while support for element/feature (2) may be found in the Specification, paragraph 0049 and original claim 2.

With respect to King, King's lead expands, and thus fails to provide a lead wherein the greatest transverse dimension of the body of the lead when outside the percutaneous introduction structure is less than a corresponding interior dimension of the percutaneous introduction structure. See, independent Claims 1, 4, 6, 8, 11 (and Claim 14), as amended. Therefore, King fails to disclose each and every element/feature of Applicant's claims.

With respect to Kuzma, Applicant is submitting herewith a Declaration of Prior Invention Under 37 C.F.R. 1.131. This Declaration establishes prior invention in this application prior to the effective date (February 13, 2001) of Kuzma.

With respect to the 102 rejection over Kohnen, Kohnen discloses a stiffening member 85 that is placed external to the paddle structure using through holes 75, 80 or 83, 84. See, Col. 5, line 9 thru Col. 10, line 17; Figures 8 and 9. However, Kohnen fails to disclose a channel extending from a proximal end of the lead to a position within the body of the lead, wherein the

channel is adapted to receive a stylet. See, Applicant's amended independent Claims 1, 4, 6, 8, 11 and 14. Thus, Kohnen's stiffening member is designed for use outside the lead, not within a chamber that is internal to the lead, as in Applicant's claimed invention. Therefore, Kohnen fails to disclose each and every element/feature of Applicant's claims.

With respect to the 102 rejection over Errico, Errico fails to specifically disclose: (1) that a greatest transverse dimension of the body of the lead when outside the percutaneous introduction structure is less than a corresponding interior dimension of the percutaneous introduction structure; and (2) a channel extending from a proximal end of the lead to a position within the body of the lead.

First, there is no teaching in Errico that the paddle lead with extending portions 101 are insertable through a percutaneous introduction structure.

Second, there is no disclosure of element/feature (1) in Errico, namely that Errico teaches a percutaneous insertable paddle lead. As discussed during the interview, Errico does not disclose a percutaneous insertion structure to make the Errico invention a percutaneously insertionable paddle lead, as taught in the present invention. Instead, Errico teaches a paddle lead with its distal end 103 having extending portions 101 for suturing to tissue/bone. The extending portions are made of sufficiently thick and durable material to allow passage of a needle and suture through them without destroying the extendable portions 101 (see, Col. 5, lines 13-19). The extending portions 101 are provided with a texture and/or color coding so that the surgeon may easily visually identify them (see, Col. 5, lines 10-13). Thus, suturing of the

extending portions 101 is consistent with a surgical implantation procedure that teaches away from the present invention, as Errico teaches that the surgeon should visually identify the colored or textured extending portions 101 in order to suture them to the patient (see, Col. 5, lines 10-13). Such suturing of these portions are thus inconsistent with a percutaneously insertionable paddle lead as taught in the present invention. Errico fails to disclose, suggest or require that the greatest transverse dimension of the body of the lead when outside the percutaneous introduction structure is less than the interior dimension of the percutaneous introduction structure.

Third, there is no disclosure of element/feature (2). Again, Applicant respectfully submits that Errico's insertion method is by surgical implantation, and not by percutaneous insertion.[2] Applicant notes that Errico appears to describe that when the distal end of the lead is surgically implanted in the spinal canal, "the wound structure may permit the inclusion of a rigid wire . . . by the surgeon, and which provides the rigidity necessary during initial implantation and advancement into the spinal canal" Col. 4, lines 46-50. This passage merely discloses that the "wound structure may permit the inclusion of a rigid wire." There is no disclosure (or showing) of where/how the wound structure "may permit the inclusion of the

[2] Errico recites a paddle-type structure with an extending portion for suturing to the tissue. Errico does not disclose or mention "percutaneous" insertion or a "percutaneous insertion structure" or "percutaneously accessing." Moreover, Errico discloses that "by techniques already known in the field of spinal surgery, the surgeon would place the electrode beneath the lamina . . ." (emphasis added). Col. 3, lines 41-44. As such, the foregoing teaching of Errico coupled with Errico's Figures 1 and 2 (that illustrate an enormous paddle structure) provide sufficient evidence that Errico's lead is not inserted percutaneously..

rigid wire." Moreover, Errico's naked reference to a rigid wire fails to disclose a channel extending from a proximal end of the lead to a position within the body of the lead (as in Applicant's claimed invention). Moreover, it appears that such rigid wire may merely assist the surgeon after the lead is initially surgically implanted between two lamina (the surgical implantation site) to advance the lead further up the spinal canal. Thus, this technique cannot lead to the conclusion that the lead is percutaneously inserted. Such conclusion is consistent with the sole purpose of Errico - providing significant extending portions for surgical suturing to surrounding tissue/bone to prevent movement of the lead. Therefore, Errico fails to disclose each and every element/feature of Applicant's claims.

Accordingly, the Applicant respectfully requests the Examiner withdraw the § 102(e) rejections of Claims 1-13 and 15-19.

IV. REJECTION UNDER 35 U.S.C. § 103

Claims 1-13 and 15-19 were alternatively rejected under 35 U.S.C. § 103(a) as being unpatentable over Errico, et al. (US 6,175,769) in view of Kohnen, et al. (US 6,249,707). The rejection is respectfully traversed.

In *ex parte* examination of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP §

2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness is established does the burden shift to the applicant to produce evidence of nonobviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP § 2142.

As previously described, Errico recites a paddle-type structure with an extending portion for suturing to the tissue. Errico's method of implant is by surgery, not percutaneous insertion. As such, the foregoing teaching of Errico coupled with Errico's Figures 1 and 2 (that illustrate an enormous paddle structure) provide conclusive evidence that Errico's lead is not inserted percutaneously. In fact, Errico recites a history of different implanting methods, from initial methods using invasive techniques (surgery), then using percutaneous methods, then reverting back to invasive techniques, and then back to percutaneous insertion techniques. The problem with the latest percutaneous techniques, as described in Errico, was the inability to fix the electrode at the appropriate location. Col. 1, lines 20-65. Thus, Errico appears to describe surgical implantation (not percutaneous implantation) of a paddle-type lead and suturing of the lead to tissue to prevent movement of the lead. As such, Errico teaches away from percutaneous insertion techniques, and thus there is no teaching or suggestion to combine Errico with Kohnen, as asserted by the Office Action. Therefore, there is no suggestion or motivation in the references to modify the reference or to combine reference teachings, and none of the references, either alone or in combination, disclose, teach or suggest the Applicant's invention as claimed.

Accordingly, the Applicant respectfully requests withdrawal of the § 103 rejection of Claims 1-13 and 15-19.

V. CLAIM 14

Claim 14 was previously withdrawn. Applicant has amended Claim 14 to recite similar features/elements as set forth in all the currently pending independent claims. Further, Claim 14 recites similar subject matter set forth in the pending claims. As such, Applicant respectfully request the Examiner to re-enter Claim 14 and reconsider Claim 14 in light of the new amendments and argument herein.

VI. CONCLUSION

As a result of the foregoing, the Applicant asserts that the remaining Claims in the Application are in condition for allowance, and respectfully requests an early allowance of such Claims.

If any issues arise, or if the Examiner has any suggestions for expediting allowance of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at ***rmccutcheon@davismunck.com***.

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

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